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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,638	05/14/2001	John Dapron	A13399 US (C06123/119964)	8768

7590 05/02/2003

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EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	9

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,638	DAPRON ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-112* is/are pending in the application.

4a) Of the above claim(s) *39-112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

1. Applicant's amendment filed 2/6/03 in Paper No. 7 is acknowledged and entered. Claims 1, 10-23, and 26-28 are amended by the amendment.

2. Claims 1-112 are pending.

3. Applicant's acknowledgement of election of Group I (Claims 1-38) in Paper No. 7 is entered.

4. Claims 39-112 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6 (Previous Office Action).

5. This application contains claims 39-112 are drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. The declaration under 37 CFR 1.132 filed 2/06/03 in Paper No. 8 is acknowledged and entered.

7. Claims 1-38 are treated on the merit in this Office Action.

Withdrawn Rejections

8. The previous rejections 35 USC 112, second paragraph, for claims 1-38 have been withdrawn in view of applicant's amendment of claims 1, 10-23, and 26-28.

9. The previous rejections under 35 USC 102(b) as being anticipated by Bioprobe International, Inc. (WO 92/03732) for claims 1-9, 12-23, and 26-30 have been withdrawn in view of applicant's argument that Bioprobe International, Inc. does not recites each and every elements in the claim specifically that 'the density of the polymer matrix on the substrate is at least $2\mu g/cm^2$'.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 103

11. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bioprobe International, Inc. (WO 92/03732).

Bioprobe teaches an assay platform that has a coating material having a number of functional binding sites available for binding of ligands for use in assay methods involving solid phase materials (pg. 3, lines 28-32; pg. 4, lines 8-29; pg. 6, lines 32-35 to pg. 7, lines 19). The coating comprise a polymer such as dextran (pg. 10, lines 7-21) that a bind to the solid phase materials. The solid phase material is polystyrene microtitre plate. A spacer is also included in

order to assist in providing specific binding site for ligand (pg. 7, lines 30-35 to pg. 8, lines 1-2; pg. 8, lines 25-35 to pg. 9, lines 1-26). The ligand is comprised of biological by active molecules to target molecules such as DNA and RNA (pg. 9, lines 27-35).

Bioprobe differs from the claimed invention by failing to include the features such as a glass substrate (Claim 11) and the ligand being a metal chelate (Claim 24).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to includes these features as elements of the assay platform of Bioprobe because the polymer of Bioprobe can be used in conjunction with solid phase materials with a wide range of ligands in qualitative and quantitative assays (pg. 3, lines 22-26). Further, these features of remaining dependent claims are either well known alternative or constitute obvious variations in parameters which are routinely modified in the art (e.g. type of substrate or ligand) and which have not been described as critical to the practice of the invention.

Since the polymer matrix of the reference contains all of the features required by the instant assay platform, i.e. the polymer bind to the substrate, the polymers are crosslinked to other polymers and attached to a ligand, it is inherent that the density of the polymer of the reference would also be at least 2 $\mu g/cm^2$.

12. Claims 22, 24-25 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bioprobe International, Inc. (WO 92/03732) in view of Döbeli et al. (US Patent 5,047,513).

Bioprobe teaches an assay platform that has a coating material having a number of functional binding sites available for binding of ligands for use in assay methods involving solid phase materials (pg. 3, lines 28-32; pg. 4, lines 8-29; pg. 6, lines 32-35 to pg. 7, lines 19). The

coating comprise a polymer such as dextran (pg. 10, lines 7-21) that a bind to the solid phase materials. The solid phase material is polystyrene microtitre plate. A spacer is also included in order to assist in providing specific binding site for ligand (pg. 7, lines 30-35 to pg. 8, lines 1-2; pg. 8, lines 25-35 to pg. 9, lines 1-26). The ligand is comprised of biological by active molecules to target molecules such as DNA and RNA (pg. 9, lines 27-35).

Bioprobe differs from the claimed invention by failing to specifically include a metal chelate as the ligand.

Döbeli teaches a metal chelate for chromatography purification of proteins (col. 1, lines 58-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay platform of Bioprobe by including metal chelate as taught by Döbeli because metal chelate, especially nickel chelate, are known to have a high specificity towards biopolymers such as peptides and proteins (Döbeli: col. 1, lines 30-33 and 42-45; col. 3, lines 48-50). The substitution of the nickel chelate ligand of Döbeli as a ligand in the platform of Bioprobe would constitute a routine choice of a well known ligand, nickel chelate being well known as an agent for protein binding.

Since the polymer matrix of the reference contains all of the features required by the instant assay platform, i.e. the polymer bind to the substrate, the polymers are crosslinked to other polymers and attached to a ligand, it is inherent that the density of the polymer of the reference would also be at least 2 $\mu g/cm^2$. Therefore, Bioprobe anticipates the claimed invention.

Response to Amendment

13. The declaration under 37 CFR 1.132 filed 2/06/03 is insufficient to overcome the rejection under 35 U.S.C. 103(a) of claims 1-38 based upon Bioprobe International, Inc. (WO 92/03732), which is henceforth be refer to as Bioprobe, as set forth in the last Office action because: the totality of the facts presented are not persuasive.

The facts presented by the declaration asserted the density of the "polymer matrix" of Bioprobe would be 300 ng/cm^2 that is base on the documented literatures of Deshpande ('*Enzyme Immunoassays from Concept to Product Development*', **1996**, Chapman & Hall, pg. 193-228) and Cole-Palmer ('*Principles in Adsorption to Polystyrene*', **1997**, NUNC™ Bulletin, No. 6, Second Ed., pg. 1-13). However, both Deshpande and Cole-Palmer density of the protein (ligand) binding to a plastic surface (substrate), and the plastic surface is polystyrene.

Bioprobe discloses '*water-soluble compounds (both monomers and polymers) including hydrophobic moieties that bind tightly to the plastic commonly used as solid phase*' (substrate) (pg. 3, lines 33-35 to pg. 4, lines 1-7). These compounds (polymer matrix) further carry reactive functional groups, which form stable covalent bonds with ligands. The ligand interacts with the target molecules. Therefore, the "platform" of Bioprobe is distinct from the "platform" of both Deshpande and Cole-Palmer (e.g. the "platform" of both Deshpande and Cole-Palmer does not include the "polymer matrix" between the ligand and the substrate) and the "polymer matrix" density calculated by both Deshpande and Cole-Palmer would not result in the density of the "polymer matrix" of Bioprobe.

Further, the declaration asserted that '*the density of "at least 2μg/cm^2 for the polymer matrix on the substrate (as claimed in claim 1) cannot be achieved through adsorption but only*

through covalent attachment of the polymer matrix to the substrate'. Therefore, the density of the "polymer matrix" of Bioprobe would not be at least 2 $\mu g/cm^2$ because the "polymer matrix" of Bioprobe is not covalently attached to the substrate.

However, the "polymer matrix" of Bioprobe is covalently attached to the substrate [e.g. '*water-soluble compounds (both monomers and polymers) including hydrophobic moieties that bind tightly to the plastic commonly used as solid phase*' (substrate) (pg. 3, lines 33-35 to pg. 4, lines 1-7)]. Therefore, the density of the "polymer matrix" of Bioprobe would be at least 2 $\mu g/cm^2$.

Response to Arguments

14. Applicant's arguments in view of the rejection under 35 U.S.C. 103(a) of Claims 1-38 as being unpatentable over Bioprobe International, Inc. (WO 92/03732) filed 2/6/03 have been fully considered but they are not persuasive.

Applicant contends that the density of the "polymer matrix" of Bioprobe would not be at least 2 $\mu g/cm^2$ but rather a density of 300 ng/cm^2 as alleges by the submitted declaration. Therefore,

It is the examiner position that the density of the "polymer matrix" of Bioprobe would be at least 2 $\mu g/cm^2$ and the declaration is not insufficient to overcome the rejection under 35 U.S.C. 103(a) of claims 1-38 based upon Bioprobe International, Inc. (WO 92/03732) as discussed above.

Further, the instant claimed invention recites a platform comprises a substrate, a polymer matrix, a binding ligand, and the target. The polymer matrix is attached to the substrate. And the

polymer matrix binds to the target through a binding ligand (e.g. the binding ligand is attached to the polymer matrix and the target). The substrate is a multiwell polystyrene plate (claims 8-9) and the polymer matrix is dextran (claims 14).

Bioprobe discloses '*water-soluble compounds (both monomers and polymers) including hydrophobic moieties that bind tightly to the plastic commonly used as solid phase*' (substrate) (pg. 3, lines 33-35 to pg. 4, lines 1-7). These compounds (polymer matrix) further carry reactive functional groups, which form stable covalent bonds with ligands. The ligand interacts with the target molecules. The coating comprise a polymer such as dextran (pg. 10, lines 7-21) that a bind to the solid phase materials. The solid phase material is polystyrene microtitre plate. Therefore, the "platform" of Bioprobe is obvious of the presently claimed platform. The density of the "polymer matrix" of Bioprobe would be inherently at least 2 $\mu g/cm^2$ because the polymer and substrate material anticipates the substrate and polymer material of the presently claimed invention.

15. Applicant's arguments in view of the rejection under 35 U.S.C. 103(a) of Claims 1-38 as being unpatentable over Bioprobe International, Inc. (WO 92/03732) in view of Döbeli et al. (US Patent 5,047,513) filed 2/6/03 have been fully considered but they are not persuasive.

Applicant alleges that Bioprobe International, Inc. (WO 92/03732) in combination of with Döbeli et al. (US Patent 5,047,513) is not obvious because the "platform" of Bioprobe is not obvious of the presently claimed platform.

It is the examiner position that Bioprobe in combination of with Döbeli et al. is obvious because Bioprobe is not obvious of the presently claimed invention as discussed above.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
May 1, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER